Appl. No.: 10/783,020 Second Preliminary Amendment

REMARKS

In this preliminary Amendment, Applicant has amended relevant paragraphs of the specification to provide the current address of the NCIMB, and provided the claims listing in proper format. It is respectfully submitted that no new matter has been introduced by the amendment.

STATEMENT OF BIOLOGICAL CULTURE DEPOSIT

Applicant respectfully submits that (1) a deposit of *Bifidobacterium longum infantis* strain HCC 35624 was made at the National Collections of Industrial and Marine Bacteria Limited (NCIMB) at Ferguson Building, Craibstone Estate, Bucksburn, Aberdeen AB21 9YA, UK on January 13, 1999 and accorded the accession number NCIMB 41003; and (2) a deposit of *Lactobacillus salivarius* strain HCC 118 was made at the National Collections of Industrial and Marine Bacteria Limited (NCIMB) at Ferguson Building, Craibstone Estate, Bucksburn, Aberdeen AB21 9YA, UK on November 27, 1996 and accorded the accession number NCIMB 40829. Enclosed please find the copies of the receipts and viability reports regarding the above-indicated deposits for Examiner's reference.

The undersigned attorney, on behalf of the Applicant of the present invention, hereby state that (1) the deposit of *Bifidobacterium longum infantis* strain HCC 35624 with the accession number NCIMB 41003 and *Lactobacillus salivarius* strain HCC 118 with the accession number NCIMB 40829 at the National Collections of Industrial and Marine Bacteria Limited (NCIMB) has been made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure; and (2) all restrictions imposed by the depositor on all restrictions to the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent.

Attorney Dockt: P66879US3

Appl. No.: 10/783,020

Second Preliminary Amendment

All claims are now present for examination and prompt action toward that end is respectfully solicited.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Date: December 30, 2004

(202) 638-6666

400 Seventh Street, N.W. Washington, D.C. 20004 Atty. Dkt. No.: P66879US3

Registration No. 22,769

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

DEC 3 0 2004

National Food B	otechnology	Centre.
University Colle	ge Cork.	•
Cork,	•	
Ireland	•	

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Role 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

NAME AND ADDRESS

L IDENTIFICATION OF THE MICROORGA	NISM
Identification of the state of	
Identification reference given by the DEPOSITOR:	Accession number given by the
DE 0310K,	INTERNATIONAL DEPOSITARY AUTHORITY:
Bifidobacterium longum infantis	NCIBAD 41000
(NFBC 35624)	NCIMB 41003
II. SCIENTIFIC DESCRIPTION AND/OR PRO	POSED TAXONOMIC DESIGNATION
The microorganism identified under I above was acce	manaind has
5 t 400 to 1725 peoc	niipaneo vy.
a scientific description	
a scientific description	•
a proposed taxonomic designation	
Mark with a cross where applicable)	•
II. RECEIPT AND ACCEPTANCE	
II. RECEIPT AND ACCEPTANCE	
3.5.7.4 at 100 at 1	
his international Depositary Authority accents the mi	compropries identified and a land about the same and the
nis international Depositary Authority accepts the mi 3 January 1999 (date of the origina	eroorganism identified under I above, which was received by it on
Coate of the dusting	at (ichosit).
Coate of the dusting	at (ichosit).
Coate of the dusting	at (chosit).
V. RECEIPT OF REQUEST FOR CONVERSION	N
V. RECEIPT OF REQUEST FOR CONVERSION be microorganism identified under Labove was received.	ved by this but a shared Day is a say
RECEIPT OF REQUEST FOR CONVERSION the inicroorganism identified under I above was receive the of the original deposit) and a request to convert if	ved by this international Depositary Authority on
RECEIPT OF REQUEST FOR CONVERSION be inicroorganism identified under I above was receive ate of the original deposit) and a request to convert if (date of receipt of request for	ved by this international Depositary Authority on se original deposit to a deposit under the Budapest Treaty was received by it or conversion)
The inicroorganism identified under I above was received the of the original deposit) and a request to convert it (date of receipt of request for	ved by this international Depositary Authority on ne original deposit to a deposit under the Budapest Treaty was received by it or conversion)
W. RECEIPT OF REQUEST FOR CONVERSION the inicroorganism identified under I above was receive late of the original deposit) and a request to convert it (date of receipt of request for	ved by this international Depositary Authority on se original deposit to a deposit under the Budapest Treaty was received by it or conversion)
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TRECEIPT OF REQUEST FOR CONVERSION TO THE INTERNATIONAL DEPOSITARY AUTHOR	ved by this international Depositary Authority on ne original deposit to a deposit under the Budapest Treaty was received by it or conversion) ITY Signature(s) of person(s) having the power to represent the
RECEIPT OF REQUEST FOR CONVERSION The inicroorganism identified under I above was receivate of the original deposit) and a request to convert it (date of receipt of request for	ved by this international Depositary Authority on the original deposit to a deposit under the Budapest Treaty was received by it for conversion) ITY Signature(5) of person(5) having the power to represent the International Depositary Authority or of authorised
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RECEIPT OF REQUEST FOR CONVERSION The microorganism identified under I above was receive at a of the original deposit) and a request to convert the convert of the original deposit of receipt of request for INTERNATIONAL DEPOSITARY AUTHOR THE CONTROL OF THE CON	ored by this international Depositary Authority on the original deposit to a deposit under the Budapest Treaty was received by it for conversion) ITY Signature(5) of person(5) having the power to represent the International Depositary Authority or of authorised

Form BP/4 (sole page)

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

National Food Biotechnology Centre, University College Cork, Cork, Ireland. INTERNATIONAL FORM

VIABILITY STATEMENT
Issued pursuant to Role 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
Identified on the following page

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED

I.	DEPOSITOR	II.	IDENTIFICATION OF THE MICROORGANISM		
Name	AS ABOVE	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: NCIMB 41003			
Adur	33:				
		Date	Athe deposit or of the transfer!		
			13 January 1999		
Ш.	VIABILITY STATEMENT				
The vi	ability of the microorganism identified under I	I above was tested o	n 13 January 1999. ² . On that date, the said microorganism		
3 X 3	viable				
	no longer viable	•	·		
	•				

- Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

Form BP/9 (first page)

tv.	CONDITIONS UNDER WHICH THE VIABILITY	TEST HAS BEEN PERFORMED ⁴
v.	INTERNATIONAL DEPOSITARY AUTHORITY	
	NCIMB Ltd., 23 St Machar Drive, Aberdeen, A24 3RY, Scotland.	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s): Date: 15 January 1999

Fill in if the information has been requested and if the results of the test were negative.

65

BUDAPEST TREATY ON THE INTERNATIONAL RELOGNITION OF THE DEPOSIT OF MICROGRAMISMS FOR THE PURPOSES OF PATENT PROCEDURE

Professor J.K. Collins, Department of Microbiology, University College Cork,

Cork, Ireland.

INTERNATIONAL FORH

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page

I. IDENTIFICATION OF THE NICROORGANISH
Identification reference given by the Accession number given by the DEPOSITOR: ACCESSION NUMBER GIVEN by the INTERNATIONAL DEPOSITARY AUTHORITY:
Lactobacillus salivarius subsp salivarius (UCC 118) NCIMB 40829
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION
The microorganism identified under I above was accompanied by:
a scientific description
X a proposed taxonomic designation
(Mark with a cross where applicable)
III. RECEIPT AND ACCEPTANCE
This International Depositary Authority accepts the microorganism identified under I above, which was received by it on 27 November (date of the original deposit) 1995
IV. RECEIPT OF REQUEST FOR CONVERSION .
The microorganism identified under I above was received by this International Depositary Authority on (date of the original deposit) and a request to convert the original deposit to a deposit under the Budapast Treaty as received by it on (date of receipt of request for conversion)
V. INTERMATIONAL DEPOSITARY AUTHORITY
Name: NCHAB Ltd Signature(s) of person(s) having the power to represent the International Depositary Authority of of authorized official(s): Address: NCHAB Ltd Signature(s) of person(s) having the power to represent the International Depositary Authority of of authorized official(s): Address: NCHAB Ltd Signature(s) of person(s) having the power to represent the International Depositary Authority of other power to represent the International Depositary Authority of December 1995

Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired.

form RP/4 (sole page)

SUBJETEST TREATH ON THE INTERNATIONAL RECOGNITION OF THE DEFENSE OF MICROSOGNIESMS FOR THE PURPOSES OF PARTIES PRODUCED THE PRODUCED TH

Professor J.K. Collins, Department of Microbiology, University College Cork, Cork, Ireland.

INTERNATIONAL FORM

VIABILITY STATEMENT issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY identified on the following page

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY STATEMENT IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICHOGRAMISM
ddress: AS ABOVE	Accession number given by the INTERNATIONAL DEPOSITARY ACTRORETY: NCIMB 40829 Date of the deposit or of the interior.
II. VIABILITY STATEMENT	27 November 1996
e viability of the microorganism ide 27 November 1996	ntified under II above was tested 2. On that date, the said microorganism was

Form 37/1 (first page)

Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability

Mark with a cross the applicable box.

; =v.	CONDITIONS	ONCES WHICH	THE VIABILITY	TEST HAS	325%	753553450
						:
						
· I:	HTERNATIONA	L DEPOSITARY	AUTHORITY			
ame: ddréss	3 ;	23 54 Mar Aberdeed	B Ltd cher Drive Scotledd Abe 1917	5i to Au	d repr short:	re(s) of person(s) having the power esent the International Depositary or of authorized official(s):
		· UK /		Dat	ie;	2 December 1995

4 Fill in if the information has been requested and if the results of the test were negative.

Form 3P/9 (second and last page)

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